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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/533,522

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Istvan Hudak

9007-1011

1625

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7590

05/23/2008

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

05/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/533,522 | Applicant(s) HUDAK, ISTVAN | |
| | Examiner JAMES W. ROGERS | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32,36-46,50-57 and 59-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32,36-46,50-57 and 59-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments to the claims filed 03/14/2008 have been entered. Applicants have amended claims 32,36,40-43,45-46 and 50-57 and entered new claims 59-65.

Response to Arguments

Applicant's arguments, see Applicant Arguments/Remarks Made in an Amendment, filed 03/14/2008, with respect to the rejections over Garibaldi have been fully considered and are persuasive. The rejections over Garibaldi under 35 USC § 102 and 35 USC § 103 has been withdrawn.

Claims 32-34,37-42,44,46-48 and 51-56, 59-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Marinovic (EP 0 280,451), for the reasons set forth in the previous office action filed 11/14/2007. A new rejection of claims 59-63 was necessitated by applicants amendments to the claims.

Regarding new claims 59-63 as outlined before Marinovic anticipates a kit for preparing a polyurethane solvent mixture.

Applicant's arguments filed 03/14/2008 have been fully considered but they are not persuasive. Applicants assert that the prepolymer of Marinovic is a polyether diurethane and as such does not meet a polyurethane. Applicants also assert that the prepolymer with its two end isocyanate groups is further reacted with a diamine chain extender resulting in a polyetherurethane urea polymer, thus applicants surmise the polymer comprises many ether polymers and two urethane terminal groups. Thus

Art Unit: 1618

applicants assert neither the prepolymer nor the complete polymer anticipate their claimed invention.

The relevance of these assertions is unclear. Firstly the pre-polymer does not restrict the final polymer and was not considered by the examiner as anticipating applicants claims. In regards to the complete polymer the repeat unit after the prepolymer is reacted with the diamine is $[-(H_2)N-R-N(H_2)-CON(H)-Z-NHCOO-(polyether)-OCONH-Z-CON(H)-N(H_2)-R-N(H_2)-]$, this repeat unit still contains urethane links ($-Z-NHCOO-$, Z is an aromatic hydrocarbon). The examiner did not wish to mislead applicants in the previous office action when describing the polymer repeat unit, rather in trying to save space and the complexity of the issue at hand only the examiner only focused on the portion of the polymer that was relevant to show that the polymer is polyurethane. As recited in the previous office action a polyurethane is any polymer consisting of a chain or organic units joined by urethane links. While the polymer also contains repeat units of urea this is not excluded from applicants claimed invention.

Applicants also assert that the prepolymer is a liquid that is hardened in situ; accordingly applicants contend the prepolymer is not dissolved in a solvent nor is it able to be dissolved in solvent and solidified upon removal of the solvent as recited in claim 59.

The relevance of this assertion is unclear. Clearly Marinovic teaches that the prepolymer in conjunction with an aqueous solution of chain extender are combined in a suitable vessel, stirred then the mixture is immediately taken up via a syringe while still being a **viscous liquid**. See page 5 lin 30-46. Thus contrary to applicant's assertions

the polymer is in solution with water and is not solid, at least immediately, thus Marinovic anticipates applicants claimed invention. It is further noted by the examiner that applicants claimed solution of polyurethane also solidifies once administered as in the tissue adhesives of Marinovic.

Applicants lastly assert in relation to Marinovic that the purpose of the reference is to prepare a polymer that serves as a tissue adhesive, and their claims recite a composition that does not stick to blood vessel walls. Applicants also assert that the "consist essentially of" language excludes a tissue adhesive.

The examiner respectfully disagrees with the above assertions by applicants. While the composition of Marinovic may indeed be useful as a tissue adhesive, the composition is never the less the same as applicants claimed invention. Furthermore it appears that both applicants claimed invention and Marinovic provide their respective effects in the same way in that both polymer solutions are liquid and then upon contact with living tissue they solidify. Nowhere within the Marinovic patent does it state that the compositions adhere to blood vessel walls, thus applicant's functional limitations for the intended use of the composition does not alleviate the Marinovic reference from being anticipatory.

Claims 32-37,39,43-51,53,56-57,59 and 61-65 rejected under 35 U.S.C. 102(e) as being anticipated by Porter (US 2002/0165583 A1), for the reasons set forth in the previous office action filed 11/14/2007. A new rejection of claims 59 and 61-65 was necessitated by applicant's amendments to the claims.

Regarding new claims 59 and 61-65 as outlined before Marinovic anticipates a kit for preparing a polyurethane solvent mixture that can be delivered by catheter.

Applicants assert that Porter fails to describe a polyurethane dissolved in a solvent or capable of solidifying upon separation from the solvent as recited within claim 59. Applicants also assert that the polymer solutions discussed by the examiner at [0088] and [0090] are only referring to a special embodiment and there is no discussion relative to polyurethane polymers or soluble polyurethane. Applicants further assert that the polyurethanes of Porter are limited to solid materials, polymerized from prepolymers then crosslinked.

The examiner respectfully disagrees with the above assertions by applicants. Porter clearly states that one embodiment includes a composition that contains a polymer dissolved in a solvent. See [0087]-[0088]. These compositions as stated by Marinovic are well known in the art as detailed previously within the same reference. Marinovic did recite the use of polyurethanes as a material useful in embolization of a vascular site, thus one of ordinary skill in the art would have readily envisaged applicants claimed dissolved polyurethane from the teachings of Marinovic. Regarding applicant's assertion that the solvents the examiner refereed to are just a small embodiment of the overall invention, the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 32,36-46,50-57,59 and 61-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter (US 2002/0165583 A1).

Applicants reiterate their arguments above in that Porter does not teach a polyurethane polymer dissolved in a solvent.

For the reasons stated above the examiner disagrees with the above assertion by applicants.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1618

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618